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Randomized controlled study of intradermal sterile water injection and intradermal lidocaine injection in obstetric analgesia

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ABSTRACT

Aims: In today's world, the increasing desire for normal and uninterrupted delivery in pregnant women has brought the need to combat labor pain and non-pharmacological techniques to the agenda again. These methods should be reconsidered in order to increase their analgesia effectiveness and to popularize their use.

Methods: In our study, intradermal sterile water (SW) injection technique, which is one of the non-pharmacological techniques, was used and the effects of intra-injection saline and lidocaine were compared. 128 patients were included in our study, and 64 patients were injected with intradermal SW and 64 patients were injected with intradermal lidocaine to provide analgesia. During labor follow-up, durations of labor phases, dilatation and effacement rates were recorded, along with Visuel analoque scale (VAS) scoring and delivery type, episiotomy application, operative delivery, cesarean section, and apgar data. At the end of the delivery, the patient's satisfaction with the procedure, the degree of pain reduction and her willingness to use this method again were questioned and recorded.

Results: Between groups, statistically significant results such as 1st hour dilatation ($p = 0.02$), 30th minute VAS ($p = 0.02$), were obtained. No maternal and fetal side effects were recorded during the study, and no significant difference was found in terms of cesarean delivery episiotomy and neonatal outcomes.

Conclusion: Lidocaine injection can be considered superior to SW injection because its positive effect on VAS score lasts longer.

Keywords: Obstetric analgesia, intradermal injection, non-pharmacological pain control techniques

INTRODUCTION

Labor pain is one of the most severe causes of pain ever defined and one of the most important components of intrapartum care is to support the pregnant woman in the control of this pain. Although birth pain is physiological, it is considered to be unbearable and has created a fear of labor pain that pregnant women think they cannot tolerate due to its social and social environment, and has led to requests for elective cesarean section.

Muscle hypoxia due to contractions, lactic acidosis, stretching and opening of the lower uterine segment, and stretching of ligaments can be shown as the cause of labor pain. In the second stage of labor, women make mentions of a sharp and continuous abdominal pain.[1] In the late first stage and second stage, the descent of the fetus and the stretching of the vagina and perineum tissues also cause pain.[2]

Ideal analgesia for delivery should be safe for mother and baby, preferably noninvasive, without adverse effects on labor. Many pharmacological and non-pharmacological techniques have been tried with these searches. Pharmacological modern analgesia was first developed in 1947 by Dr. Simpson using ether and chloroform. And then until today, many methods such as epidural, spinal, paracervical pudental have been tried.[3,4] Today, epidural analgesia is used by pregnant women and doctors in many clinics. However, side effects such as nausea, urinary retention, numbness and decreased ability to strain, and prolongation of the labor phases have been reported.[5-9]

In addition, many non-pharmacological methods have been tried until today. Massage, hot and cold compresses, transcutaneous electrical nerve stimulation (TENS) and

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intradermal sterile water injections (SWI) are considered to be the main ones. The advantages of these techniques are that they are easily accessible, inexpensive and have a low side-effect profile.[10,11]

Intradermal injection has been reported as a highly effective and easy-to-use method in many studies.[12,13] The effect of intradermal injection on labor pain is explained by Gate control theory (GCT). Intradermal blisters formed by injections reduce pain by activating large-diameter fibers carrying the sense of touch and inhibiting small-diameter fibers carrying the pain message. Theory of melzack and wall on pain percetion mentions that non-painful input closes nerve gates to other painful inputs and prevents pain sensation.[24]

A cochrane study of labor pain control, the effects of intradermal and subdermal sterile water injections were compared with a control group. The results of seven studies with 766 samples were analyzed. Four studies assessed intradermal injection, two studies assessed subdermal injection, and one study assessed both intradermal and subdermal injections of sterile water. Sterile water injection reduced labor pain by at least 50%, while the placebo reduced labor pain by 20%.[14]

In some studies, SWI has been reported to be effective in reducing labor pain as well as reducing cesarean section rates. In a multicenter study conducted on 1.866 women who gave birth in Australia, it was found that intradermal injection of 0.1- 0.3 cc sterile water applied to the sacral region significantly reduced the rate of cesarean section.[25]

Previous studies have reported that the effect of intradermal sterile water injection occurs rapidly, but is short-lived, and needs to be repeated.[12-15]

We have thus designed a study to reevaluate the analgesic efficacy of intradermal injection. We planned to apply intradermal lidocaine injection to our patients in order to eliminate the feeling of discomfort and pain in the injection sites mentioned in the studies in which SWI was applied and to see its effect on the duration of analgesia.

METHODS

The study was carried out with the permission of the İstanbul Zeynep Kamil Women and Children Diseases Training and Research Hospital Ethics CommitteeAll procedures were carried out in accordance with the ethical rules and the principles of the Declaration of Helsinki.

Our study was planned as a prospective randomized controlled study on pregnant women with 3-5 cm cervical dilatation, who entered the active phase of labor and applied to the Obstetrics Clinic in İstanbul Zeynep Kamil Research and Education Hospital between February 2016 and March 2016. Multiple pregnancies, pregnancies with malpresentation, pregnancies who were not between 37-42 weeks of gestation, who had undergone uterine surgery, and pregnant women with systemic disease and CPD examination were not included in the study. 128 pregnant women were included in our study.

Demographic, clinical and biochemical findings of the cases were recorded. Before the procedure, fetal heart rate monitoring was applied to each patient and it was determined that there was a reactive heart beat pattern. In addition, the amplitude, frequency and duration of uterine contractions were determined. After the hospitalization of our patients, it was decided which group to be included in the computer-based randomization system and included in the study. In our study, our patients were divided into two groups. The first group received intradermal SW injection, and the second group received intradermal lidocaine injection, at the injection site from 1 to 10. Amniotomy with appropriate obstetric indications and induction of labor with oxytocin were applied to the patients whose birth follow-up was performed by the delivery room team in both groups. Patients who entered the active labor phase and stated that they had low back pain, injections were given the special region. The region in the shape of an equilateral quadrangle, which is located among posterior superior iliac spines, gluteal muscles, and spinous process of vertebra L4; 3 cm lower and 1 cm medial from superior iliac spines and spines were marked. Injections were given to both groups simultaneously and at the peak point of contractions by obstetricians. The process was terminated when 4 small bullae were observed on the waist. VAS (visual analogue scale) scoring was performed for low back pain before the procedure was performed on the patient.

Visual analogue scale (VAS): the VAS is a 10 cm (100 mm) ruler on which the patient marks the pain, with painlessness on one end and excruciating pain on the other. The patient is told that there are two endpoints and that he or she should mark anywhere between these points that matches the severity of the pain. The distance between the point where the patient marked the pain and the pain-free interval is measured in cm and recorded. It is stated that the VAS has a high sensitivity and reliability in the measurement of pain severity.[26]

Afterwards, if the patient did not give birth at 15-30-60-120-180 minutes, the VAS score was asked again and the vaginal examination was performed and recorded. The delivery of the patient was done by the team working in the delivery room. Type of delivery, gender, weight, 1st and 5th minute APGAR scores, and effects and complications during delivery were recorded. The postpartum patient was asked to rate her satisfaction with the procedure, whether she would like to use this procedure if she gave birth again, and her discomfort

While evaluating the findings obtained in the study, SPSS version 17 program was used for statistical analysis. While evaluating the study data, in addition to descriptive statistical methods (mean, standard deviation), student's t test was used for comparison of normally distributed parameters between groups in comparison of quantitative data. Paired sample t-test was used for within-group comparisons of normally distributed parameters. chi-square test and fisher's exact chi-square test were used to compare qualitative data. The

results were evaluated at the 95% confidence interval and the significance level of p<0.05.

RESULTS

In this double-blind study, considering the exclusion criteria, intradermal injections of 64 sterile water and 64 lidocaine were applied to 128 pregnant women in total. In the results obtained, there was no difference between the groups in demographic data (Table 1).

Table 1. Demographic characteristics of the groups

	SW n: 64 mean ± SD	Lidocaine n: 64 mean± SD	p
Age	24.5 ±5.3	24.5±5.5	0.9
Length	161.4±5.7	161.03±5.5	0.9
Weight	71.4±8.7	73.5±9.8	0.4
Gravity	1.9±1.1	1.6±1.0	0.3
Parity	0.53±0.9	0.50±0.7	0.9
GW	39.4±1.33	39.4±1.31	0.9
Duration of education	7.2±3.5	6.5±3.6	0.5

GW: Get well soon, SW: Sterile water, n: Number, SD: Standard Devision

During the evaluation, it was determined that there was no statistical difference between the two groups in terms of dilatation (p=0.15) and effacement (p=1) during the application, and in terms of VAS scores before the procedure (p=0.72)

Patients with a training period of <8 years and >8 years were divided into two groups. Our patients, who were divided into two groups according to their education levels, were compared with each other in terms of the scores they gave to VAS scores and their compliance scores during labor and no statistically significant results were found (p>0.05).

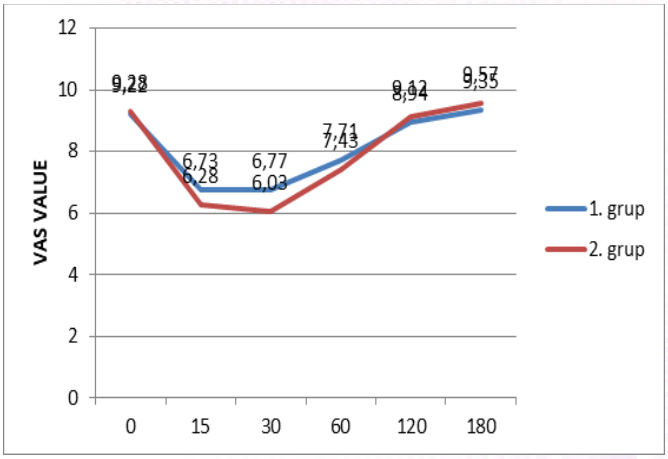

Figure 1. The VAS Score distribution between the groups

87.5% of our study patients mentioned a significant reduction in low back pain within 15 minutes after intradermal injection of lidocaine. While this analgesic effect at a rate of 91.9% reached the 30th minute, 75.4% of the pregnant women felt the analgesia effect in 60 minutes, unlike the 1st group study patients. 14% of pregnant women who did not give birth and continued labor felt the analgesia effect at 180th minute. Our patients stated that their pain started again after an average of 70 minutes. Comprasion of Vas scores between two groups are shown in Table 2 and Figure 1. Also obstetric and neonatal outcomes have been compared for both groups in Table 3.

Table 2. Comparison of VAS scores

	SW n mean ± SD	Lidocaine n mean± SD	p
Application VAS	9.22 ± 1	9.28 ±1	0.72
15.Min VAS	6.73 ±1.88	6.28 ±1.82	0.17
30.Min VAS	6.77±1.74	6.03±1.79	0.02*
1. Hour VAS	7.71±1.64	7.43±1.71	0.35
2. Hour VAS	8.94±1.16	9.12±1.30	0.50
3. Hour VAS	9.35±0.93	9.57±0.73	0.36
Vas Diff. 15. Min.	-2.41±1.92	-2.68±1.78	0.40
Vas Diff. 30. Min.	-2.45±1.79	-3.24±1.78	0.01*
Vas Diff. 60. Min.	-1.53±1.68	-1.83±1.60	0.32
Vas Diff. 120 Min.	-0.37±1.31	0.08±1.60	0.37
Vas Diff. 180 Min.	0.10±1.02	0.45±1.17	0.24

Diff: Difference, n: Number, SD: Standard Devision

Table 3. Comprasion of obstetrical and neonatal outcomes

	SW	Lidocaine	P
Dilation cm during application	4.89	4.69	0.15
1.Hour dilation cm	6.98	6.30	0.02*
2.Hour dilation cm	7.66	7.08	0.13
3.Hour dilation cm	8.25	7.44	0.14
Labor induction	%87.5	%93.8	0.46
Amniotomy	%30.6	%39.1	0.93
Episiotomy	%62.5	%73.4	0.44
Caesarean	%4.7	%4.7	0.55
Operative Birth	%3.1	%7.8	0.06
Baby weight (gr)	3199	3248	0.8
Apgar 1.	7.77	7.86	0.3
Apgar 2.	8.88	8.91	0.6
Total	64	64	

SW: Sterile water

At the end of the birth, a mini-questionnaire was arranged for the patients, and they were asked to score from 1 to 10 on the scales, the degree of satisfaction, the degree of pain relief and the desire to use the same method again, and it was recorded. There was no significant difference between the two groups in these parameters (p>0.05). In the previous studies, for the discomfort and pain sensation at the injection site, 24.7% of the patients in the SW group, whose VAS scoring was performed, described pain at the injection site, while 21.4% of the patients in the lidocaine group described a pain. No significant difference was found between the groups in the analysis.

DISCUSSION

Fear of labor pain increases the rates of elective cesarean section and also creates negative situations on active labor. It has been reported that obstetric analgesia reduces both maternal and perinatal morbidity rates.[27] Ideal analgesia for childbirth should be safe for both mother and baby, preferably noninvasive, without adverse effects on labor. Although the ideal analgesia method with all these features has not been developed yet, the search continues. Today, non-

pharmacological obstetric analgesia techniques have come to the fore again due to the patients' search for natural birth, and the need to develop new techniques has been felt.

Intradermal water block (0.5-.1 ml) consists of 4 small sterile water bubbles into the skin. One is placed on the posterior superior iliac spine, the other two are placed 3 cm below. In the studies, It is mentioned that intradermal SW injection is painful and uncomfortable during the injection and it causes severe pain for 30 seconds.[28,29] The other common problem mentioned is that the analgesia effect is short-lived. We planned this study by considering reducing the feeling of discomfort during the injection and increasing the duration of the analgesia effect with intradermal lidocaine injection instead of intradermal SW injection.

In randomized studies, the effects of intradermal water blocks application and alternative non-pharmacological methods (TENS, activity massage, bath) on pain in the lumbar region at birth were compared. In all studies, intradermal water block application was found to significantly reduce low back pain.[23] It was found that the relief in pain continued for 120 minutes when the application was not repeated, and most of the women wanted the application to be repeated.[30] In Fogarty's (2008) review, it was found that sterile water for intradermal injection had a strong analgesic effect on low back pain at birth and its use did not cause any side effects.[23] In addition, the same study found the effect of the application on fetal rotation, pelvic floor muscles and cervical dilatation. Similar results were found in our study. In both groups, over 80% of the patients were relieved at the 15th minute, and a significant decrease in VAS scores was observed. It was found that the patient who was injected with lidocaine in the 2nd group at 30 minutes was statistically superior to the 1st group in terms of pain relief (p=0.01). While 91% of the 2nd group patients described a decrease in VAS scores compared to the first minute, 83% of the 1st group patients mentioned a decrease in their VAS scores. Intradermal SW injection also contributed to cervical dilatation in our study. The 1st group 1st hour cervical dilatation was found to be higher than the 2nd group and it was statistically significant (p=0,02).

In a similar randomized study of 272 cases, Trolle, Moller, Kronberg, and Thomsen (1991) reported that a remarkable analgesic effect was noted in the experimental group administered sterile water injection, even 1 and 2 hours after administration, compared to the placebo control group.[19] In the same study, it was stated that no side effects of the technique were observed, and that the mothers were satisfied with the application and that they would like to use the method again in case they give birth again.[19] Similar results were obtained in our study. While the analgesic effect was still continuing in 66% of the patients in the 60th minute VAS scoring, and lower VAS values were recorded in the group using SW, 75% of the patients in the 2nd group still mentioned analgesia effectiveness at the 60th minute. No maternal-fetal side effects were recorded during our study, and no difference was found between Apgar scores, operative delivery rates and cesarean delivery rates. In the satisfaction scales, the results were recorded as follows: 68.8% of the patients in the 1st group stated that they were satisfied with the procedure by giving a score of 6 and above on the satisfaction scale, and 64.2% of them gave a score of 6 or higher for the question of whether they would like this procedure if they gave birth again. 71.9% of the patients in the 2nd group stated that they were satisfied with the procedure by giving a score of 6 and above on the satisfaction scale, and 64.1% of them gave a score of 6 or above to the question of whether they would like this procedure if they gave birth again.

Martensson and Wallin, in their review of eight randomized controlled trials on 828 women, found that SWI administration was associated with significantly reduced cesarean rates.[18] In our study, the cesarean rates for both groups were the same, and they were similar to the primary cesarean rates in our hospital. Birth patterns according to hours between two groups are shown in Figure 2. While there are no studies on intradermal lidocaine injection, it can be considered superior to SW injection because its positive effect on VAS score lasts longer and its analgesia efficiency is more pronounced.

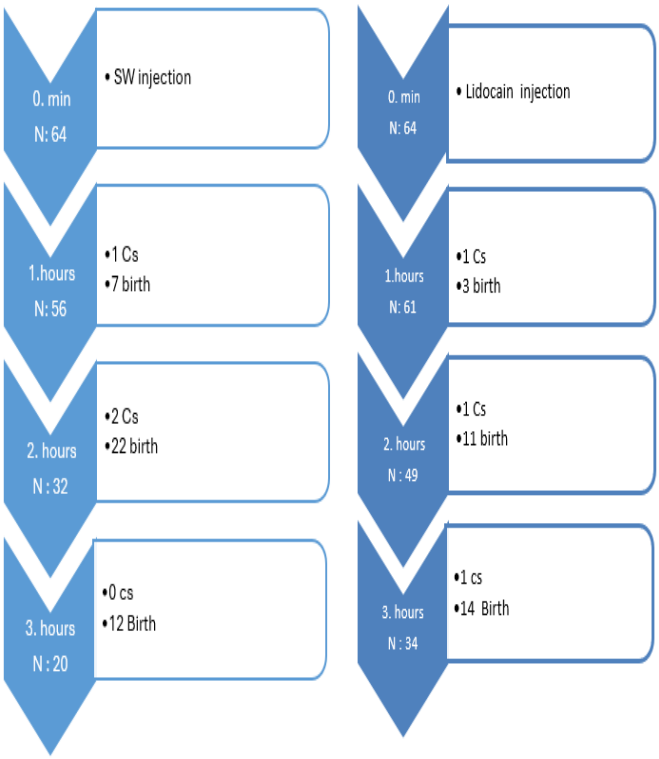

Figure 2. Birth patterns according to hours between two groups

CONCLUSION

Although there are many studies in the literature investigating non-pharmacological applications for the control of labor pain, no study has been found on pain control with intradermal lidocaine injection. As a result of the present study, both SWI application and intradermal lidocaine injection cause a significant decrease in pain scores, it is preferred by women, and most of them will use it again if necessary. The most important thing is that it significantly reduces the low back pain experienced at birth without any side effects on the fetus and mother. For these reasons, SWI or intradermal lidocaine injection may be preferred more as a non-pharmacological pain control method used to reduce low back pain during labor. It was concluded that more studies could be designed for pain control related to intradermal lidocaine injection.

ETHICAL DECLARATIONS

Ethics Committee Approval

The study was carried out with the permission of the İatanbul Zeynep Kamil Women and Children Diseases Training and Research Hospital Ethics Committee

Informed Consent

All patients signed and free and informed consent form.

Referee Evaluation Process

Externally peer-reviewed.

Conflict of Interest Statement

The authors have no conflicts of interest to declare.

Financial Disclosure

The authors declared that this study has received no financial support.

Author Contributions

All of the authors declare that they have all participated in the design, execution, and analysis of the paper, and that they have approved the final version.

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